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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0023; FRL-9935-81]

Choline Chloride; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the Choline Chloride (Acetyl Choline) in or on all food commodities when applied/used pre-harvest and used in accordance with label directions and good agricultural practices. CP Bio, Inc., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of Choline Chloride.

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2015-0023, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the

Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *BPPDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2015-0023 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2015-0023, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Background and Statutory Findings

In the **Federal Register** of March 4, 2015 (80 FR 11611) (FRL-9922-68), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 4F8287) by CP Bio, Inc., 4802 Murrieta Street, Chino, CA 91710. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of Choline Chloride in or on all food commodities (when applied pre-harvest). That document referenced a summary of the petition prepared by the petitioner CP Bio, Inc., which is available in the docket, *http://www.regulations.gov*. There were no substantive comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue.... " Additionally, FFDCA section 408(b)(2)(D) requires that the Agency consider "available information concerning the cumulative effects of a particular pesticide's residues" and "other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability, and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

A. Overview of Choline Chloride

Choline Chloride is an ammonium salt that readily dissociates into two constituents – Choline and Chloride. It presents as a white crystalline solid that is odorless. Each constituent is ubiquitous in the environment, constitutes a regular part of the human diet, and serves many critical functions in the human body. Choline is found in such foods as egg yolk, vegetables and animal fat. It is a precursor of a vital neurotransmitter; and it is critical for the structural integrity of cell membranes and various metabolic functions. Chloride is also a regular part of the human diet, particularly as a constituent of edible salt, and serves many functions in human biology. Chiefly, Chloride is an essential electrolyte responsible for maintaining acid/base balance, transmitting nerve impulses and regulating fluid in and out of cells.

Choline Chloride is already approved for use by EPA as an inert ingredient in pesticide products without numerical limitation for pre-harvest use (40 CFR 180.920). Additionally, Choline Chloride is designated as GRAS (Generally Recognized as Safe) and is approved by the

Food and Drug Administration (FDA) as a human nutrient under 21 CFR 182.8252 and as a nutrient in animal feeds under 21 CFR 582.5252.

As a biopesticide, Choline Chloride is considered a plant growth regulator (PGR) intended for use to increase growth and decrease stress in growing crops. It has a non-toxic mode of action; and as with most PGRs, it is applied at low concentrations because use at high concentrations result in detrimental effects to the plant.

B. Biochemical Pesticide Toxicology Data Requirements

All applicable mammalian toxicology data requirements supporting the petition to establish an exemption from the requirement of a tolerance for the use of Choline Chloride as an active ingredient for use as a PGR on food crops have been fulfilled. All acute toxicology data requirements were fulfilled through guideline studies. The Acute Oral Toxicity Category is III; all other categories are IV. Additionally, the information submitted in support of the application indicate that Choline Chloride is non-mutagenic and that it is not subchronically or developmentally toxic. Subchronic oral toxicity, mutagenicity and developmental toxicity data requirements were satisfied through scientific literature. Subchronic dermal and inhalation requirements were waived for lack of exposure. (A complete assessment of the toxicology submission for Choline Chloride can be found in the docket.)

C. EPA's Safety Determination

EPA evaluated the available toxicity and exposure data on Choline Chloride and considered its validity, completeness, and reliability, as well as the relationship of this information to human risk. A full explanation of the data upon which EPA relied and its risk assessment based on that data can be found within the August 11, 2015, document entitled "Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Choline Chloride." This document, as well as other relevant information, is available in the docket for this action as

described under **ADRESSES**. Based upon its evaluation, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of Choline Chloride. Therefore, an exemption from the requirement of a tolerance is established for residues of Choline Chloride in or on all food commodities when applied pre-harvest and used in accordance with label directions and good agricultural practices.

IV. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

Food Exposure. Dietary exposure to the pesticidal residues of Choline Chloride is expected to be negligible. (1) Choline Chloride is a PGR and is necessarily applied at low concentrations. (High concentrations result in detrimental effects to the plant).
(2) Choline Chloride biodegrades rapidly. A MITI-I test demonstrated that Choline Chloride is 93% degraded within 14 days. (3) As a salt, Choline Chloride dissociates readily when in contact with water, making its persistence as a residue even more unlikely.

Should exposure occur, however, minimal to no risk is expected for the general population, including infants and children. Notably, humans are already dietarily exposed to Choline Chloride. It is produced endogenously, and is found naturally in foods in the human diet. Indeed, it is considered an essential human dietary component, serving critical functions in nerve transmission, cell membrane integrity and lipid metabolism.

Drinking Water Exposure. No significant residues of Choline Chloride are expected in drinking water when products are used according to label instructions. The active ingredient is applied terrestrially at low concentrations; it is very soluble in water; and it biodegrades rapidly, once applied. As such, any residues of Choline Chloride in drinking water are anticipated to be negligible.

It should be additionally noted that both Choline and Chloride, the constituents of Choline Chloride, are ubiquitous in the environment; and there is a long history of incidental, but minor, exposure through drinking water.

B. Other Non-Occupational Exposure

Non-occupational exposure to Choline Chloride residues are not expected. Choline Chloride is not intended for use in residential settings; it is intended for agricultural use only. Nonetheless, even in the event of incidental exposure, minimal to no risk is expected due to the low toxicity of the chemical as explained in the risk assessment found in the docket.

V. Cumulative Effects from Substances with a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found Choline Chloride to share a common mechanism of toxicity with any other substances, and Choline Chloride does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that Choline Chloride does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism

of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative.*

VI. Determination of Safety for U.S. Population, Infants and Children

FFDCA section 408(b)(2)(C) provides that, in considering the establishment of a tolerance or tolerance exemption for a pesticide chemical residue, the EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) provides that the EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure, unless the EPA determines that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor. In applying this provision, the EPA either retains the default value of 10X, or uses a different additional or no safety factor when reliable data are available to support a different additional or no safety factor.

Because there are no threshold effects associated with this biochemical, an additional margin of safety for infants and children is not necessary.

EPA has determined that there are no foreseeable dietary risks to the U.S. population, including infants and children, from the pesticidal use of Choline Chloride. Exposure to the residues of Choline Chloride is expected to be negligible due to the low concentrations associated with its use as a PGR, its high solubility and its rapid biodegradability. Moreover, any exposure to Choline Chloride residues are not expected to pose a risk. No toxic endpoints have been identified for Choline Chloride. There has been a long history of significant human dietary

and endogenous exposure without documented incident. And the constituents of Choline Chloride are known to be readily metabolized.

VII. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for Choline Chloride.

VIII. Conclusions

Based on its assessment of Choline Chloride, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from

aggregate exposure to Choline Chloride. EPA is therefore establishing an exemption from the requirement of a tolerance for residues of Choline Chloride in or on all food commodities when applied pre-harvest in accordance with label directions and good agricultural practices.

IX. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq*., nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct

effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

X. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq*.), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 1, 2015.

Jack E. Housenger,
Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Add § 180.1334 to subpart D to read as follows:

§ 180.1334 Choline Chloride; Exemption from the Requirement of a Tolerance.

An exemption from the requirement of a tolerance is established for residues of Choline Chloride in or on all food commodities when Choline Chloride is applied pre-harvest and used in accordance with label directions and good agricultural practices.

[FR Doc. 2015-31464 Filed: 12/15/2015 8:45 am; Publication Date: 12/16/2015]